

### **REMARKS**

This responds to the Office Action mailed on February 23, 2005.

Claims 1 – 16 are hereby canceled without prejudice or disclaimer. Claim 17 is amended and claims 23 – 40 are added; claims 17-40 are now pending in this application.

#### **Double Patenting Rejection**

Claim 1 was rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of Lange et al. (US 6,712,789). Claim 12 was rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of Lange et al. (US 6,712,789). Claims 1 and 12 were canceled without prejudice or disclaimer thereby rendering the rejection moot. Applicant reserves the right to reinstate the claims and/or file a continuation on this claimed subject matter.

#### **§§102, 103 Rejection of the Claims**

##### ***Claims 1 - 16***

Claims 1, 9, and 10-13 were rejected under 35 U.S.C. § 102(b) for anticipation by Walker et al. (US 5,755,693). Claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of Pohndorf et al. (US 5,441,504). Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of West (US 6,322,541). Claims 2-7 and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker (as applied to claims 1 and 10 above) in view of Pohndorf et al. (US 5,441,504). Claim 8 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of West et al. (US 6,322,541).

Claims 1 - 16 were canceled without prejudice or disclaimer thereby rendering the rejection moot. Applicant reserves the right to reinstate the claims and/or file a continuation on this claimed subject matter.

*Claims 17 - 22*

Claims 17-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walker in view of West et al. (US 6,322,541). Applicant respectfully traverses the rejection. The references fail to establish all elements of the claims, fail to enable the subject matter of the claims. Furthermore, there is no objective motivation to combine the references.

For instance, Applicant cannot find in either reference a releasable side port releasably coupled with the sheath. Applicant notes that the Office Action mentions “[t]he patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a releasable side port assembly (19, 20) being used with a vascular access system (10). (See Col. 2, line 46 through Col. 3, line 8).” Page 8, Office Action. Applicant respectfully traverses this assertion. West, instead, mentions the hub and end cap structure which allows for a *compressive connection*. For example, West states “the hub 22 and the end cap 24 include a means for compressive connection therebetween, such as a snap-fit connection or a threaded connection.” West, Col. 3, Lines 4 – 7. However, there is no mention of a releasable side port assembly recited in the claims. Applicant cannot find any such teaching in West for the side port assembly 19, 20.

Applicant further traverses the rejection because the cited reference is not enabling. To be properly considered as prior art in an obviousness determination, a patent must be enabling. *Ashland Oil, Inc. v. Delta Resins and Refractories*, 776 F.2d 281, 297, 227 USPQ 657 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). The cited references fail to enable a releasable side port that is releasably coupled with the sheath.

Furthermore, the Office Action fails to provide an objective motivation to combine the references. Notwithstanding that the references fail to establish all of the elements of the claims as discussed above, Applicant submits the Office Action fails to establish a *prima facie* of obviousness, because there is no *objective* motivation to combine the references. According to the Office Action “it would be obvious . . . since the use thereof would provide an improved introducer with an attachable side port for a flush or injection.” Office Action, Page 7. Applicant notes that no objective support is provided for such an assertion. Applicant

respectfully submits that such an assertion cannot legally support a motivation to combine the references.

As the Federal Circuit has stated: “Virtually all inventions are combinations of old elements. . . . If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.” *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal Inc.*, 56 U.S.P.Q.2d 1641, 1644 (Fed. Cir. 2000), quoting *In re Rouffet*, 149 F.3d 1350, 1357-1358, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998).

Instead, motivation to combine the references must be found in the prior art, and not based on Applicant’s disclosure. Furthermore, a showing of a suggestion, teaching, or motivation to combine prior teachings “must be clear and particular . . . Broad conclusory statements regarding the teaching of multiple references, standing alone, are not ‘evidence.’” *In re Dembiczak*, 175 F.2d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

Applicant submits that the rejection fails to rely on an objective motivation to combine the references, and in fact appears to be relying on the personal knowledge of the Examiner. According to the Office Action, “the Examiner determines that . . . the combination . . . would provide an improved introducer.” Page 7, Office Action. Since the Office Action is relying on the personal knowledge of the Examiner, Applicant requests an affidavit supporting the assertions as required by 37 CFR 1.104(d)(2). Applicant further traverses the assertion under MPEP 2144.03.

Applicants respectfully traverse the rejection because the rejection fails to provide an objective motivation to combine. Reconsideration and allowance are respectfully requested.

#### *Claims 23 – 40*

Claims 23 – 40 are new claims added herewith. No new matter has been entered. Applicant submits that claims 23 – 38 are patentable over the cited art. Applicant cannot find in the cited references a side port assembly or coupling member releasably coupled with a portion of the sheath.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 10/804,596

Filing Date: March 18, 2004

Title: INTRODUCER HAVING A MOVABLE VALVE ASSEMBLY WITH REMOVABLE SIDE PORT

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Dkt: 905.020US2

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,


MICHAEL LANGE ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 359-3276

Date 7/22/05

By

  
Catherine I. Klima-Silberg  
Reg. No. 40,052

**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 22nd day of July, 2005.

PATRICIA A. HULTMAN

Name

  
Signature